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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MELTON B. AFFRIME, CHRISTOPHER R. BANFIELD,
SAMIR K. GUPTA and DESMOND PADHI

Appeal 2007-3897
Application 09/760,588
Technology Center 1600

Oral Hearing Held: February 12, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Tuesday, February 12, 2008, commencing at 9:24 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Carol A. Lowe, RPR, CCR No. 0313084, Notary Public.

JUDGE SCHEINER: Good morning.

MR. BERMAN: Good morning.

JUDGE SCHEINER: Would you like to introduce your -- well, first let me tell you we have an observer this morning.

MR. BERMAN: Good morning.

JUDGE SCHEINER: And would you like to introduce your colleagues for the record?

MR. BERMAN: I would be pleased to. I'm Paul Berman from Covington & Burling. This is my colleague, Natalie Derzko, also from Covington & Burling. Henry Haddad and Barry Jacobson from the assignee, Schering-Plough Corporation. And another colleague, Brook Harper, from Covington & Burling.

JUDGE SCHEINER: Good morning.

MR. BERMAN: Thank you very much.

JUDGE SCHEINER: Whenever you're ready. You have 20 minutes.

MR. BERMAN: Thank you. May it please the Board. This is a pure inherent anticipation case solely under Section 102(e) of the statute with respect to a single reference, the 274 patent to Kou which is also owned by the assignee Schering.

A terminal disclaimer has been filed to obviate any obviousness-type double patenting rejection to avoid even the appearance that this is a pharmaceutical company trying to Evergreen its patents.

Because the Kou reference and this application are commonly owned this application is entitled to the benefit of Section 103(c) of the statute of the patent code in this regard.

We did exactly what the statute encourages in the context of a very difficult and challenging drug development problem. It turns out that desloratadine, the active ingredient in the Kou formulation, is a very active molecule and degrades in the presence of certain excipients. The Kou invention is directed to and claims formulations that solve that degradation problem.

What Schering did was to proceed to file a patent application on the formulation that's the Kou patent rather than waiting for the necessarily subsequent clinical trials that would develop a safe and effective pharmacokinetic profile.

We could have waited to file both inventions, if you will, in the same application. We thought we were protected by 103(c) and that 103(c) encouraged us to file the formulation patent first which we did.

If we had waited to file them at the same time, there would be no prior art Kou reference at all. We believe that we're being penalized unfairly and wrongly for having engaged in a course of conduct that the statute encourages.

The invention of this application really is the discovery of a target pharmacokinetic profile that would be safe and effective. Once the skilled clinician has that profile which is entirely missing from the prior art Kou reference, then she would know what to do in light of the relevant factors to target it. These factors include -- yes.

JUDGE SCHEINER: Can I interrupt for just a second?

MR. BERMAN: Please.

JUDGE SCHEINER: The claim -- now, I understand that this -- Kou is the stabilized desloratadine. But the original patent on this was

Vilani; is that correct?

MR. BERMAN: Yes.

JUDGE SCHEINER: Now, would that have the same PK profile?

MR. BERMAN: Not necessarily.

JUDGE SCHEINER: Not necessarily. Is it -- okay.

JUDGE FREDMAN: Is it the same molecule?

MR. BERMAN: I'm sorry.

JUDGE FREDMAN: Is Vilani the same molecule, desloratadine?

MR. BERMAN: The Vilani claims the same molecule, desloratadine, as we're talking about here but different formulation.

JUDGE SCHEINER: But my question is if the -- now, the claim on its -- at first glance just says desloratadine. It doesn't -- I understand that your specification references the Kou patent for -- that -- that the -- the clinical trials that are described in the specification were done with the formulation that's described in the Kou patent.

MR. BERMAN: Yes.

JUDGE SCHEINER: But the claim apart from these -- leaving aside for a moment the PK profile, the claim just says desloratadine. It's not a particular -- it doesn't recite a particular formulation.

So my question is whether or not the desloratadine that's described in the original application, the Vilani, would have that same PK profile.

MR. BERMAN: Not necessarily. There are a range of factors that the skilled clinician would need to take into account in order to target

the specified pharmacokinetic profile.

JUDGE SCHEINER: Okay.

MR. BERMAN: These include the dosage amount, the dosage size which is not specified in Vilani at all, the number of administrations per day, the weight and age of the patient as well as the pharmacokinetic characteristics of desloratadine on which Kou and, parenthetically, Vilani are silent and which are taught by this application; that desloratadine has lineal pharmacokinetics and exhibits dose proportionality example.

With that information and those factors a skilled clinician would be able to target a pharmacokinetic profile.

JUDGE SCHEINER: Well, let me ask you. Also, I notice that originally in this case the claims were all directed to producing this particular PK profile. And somewhere along the line it became targeting the profile. Can you elaborate on that a bit?

MR. BERMAN: I can elaborate on that. The primary reason for that, Your Honor, is that with respect to any method of administration claim, whether the claim be phrased as a method for treating something or a method for targeting something, the skilled clinician is striving for a result which may or may not be achieved. It's -- they're all goal oriented claims. And --

JUDGE SCHEINER: Well, are we talking about a mental step here? If you don't intend to target this profile, you're not within the scope of the claim?

MR. BERMAN: It's more than a mental step. It requires administration here. And that's -- each one of the claims requires administering a pharmaceutical composition or formulation comprising

desloratadine to -- for the purpose of targeting a particular --

JUDGE SCHEINER: And the specification indicates that five -- five mgs per day in single dose or divided doses will accomplish that or will produce that profile. Is that correct?

MR. BERMAN: Not necessarily. It will in some people, but in others it will not.

JUDGE SCHEINER: Okay.

MR. BERMAN: Let me give you -- some examples include age of the patient, whether -- and you indicated five milligrams once a day. The specification also teaches two-and-a-half milligrams in -- twice a day, other divided doses which would surely result in a different pharmacokinetic profile.

In addition, note that a single administration as another example provides a time to maximum concentration of four hours whereas in the steady state the T max is three hours.

As another example, this specification teaches that for elderly people over 65 the half-life is about 30 percent longer.

So depending on these factors a different pharmacokinetic profile would result. And a skilled clinician would be able to take these factors into account to achieve the specified, claimed pharmacokinetic profile.

JUDGE FREDMAN: From the point of inherent anticipation the question I would wonder is -- the drug was available in 1990. When did this drug first come out?

MR. BERMAN: It was subsequent to these applications. If you'll excuse me --

JUDGE FREDMAN: The desloratadine was not available before 2000?

MR. BERMAN: No. It was approved in 2001.

JUDGE FREDMAN: So loratadine was earlier but not desloratadine.

MR. BERMAN: Yes. That's correct.

JUDGE SCHEINER: Okay.

MR. BERMAN: And -- yes. Loratadine is Claritin.

JUDGE FREDMAN: Right.

MR. BERMAN: And Desloratadine is --

JUDGE FREDMAN: Clarinex.

MR. BERMAN -- Clarinex.

JUDGE SCHEINER: Clarinex.

JUDGE FREDMAN: Okay.

JUDGE SCHEINER: So it wasn't then.

MR. BERMAN: It was not.

JUDGE SCHEINER: Okay.

MR. BERMAN: Again, this is prior art only under 102(e).

JUDGE SCHEINER: Okay.

MR. BERMAN: Thank you. I appreciate that.

JUDGE SCHEINER: But the earlier formulation was not available either. I understand that this desloratadine is Clarinex, but the -- I assume that's with the -- as formulated in Kou.

MR. BERMAN: Correct. Desloratadine --

JUDGE SCHEINER: And it wasn't available -- desloratadine was not --

MR. BERMAN: Not available --

JUDGE SCHEINER: -- available before 2001.

MR. BERMAN: Right.

JUDGE SCHEINER: Okay.

MR. BERMAN: This is a different invention from Kou. Kou is to a formulation, not a method of administration. Formulations and methods of administration have been separately patentable for a long, long time. And we believe that the examiner's decision would upend this settled aspect of patent law.

The logic of the examiner's decision would have the Kou disclosure which is silent on pharmacokinetics, silent on the behavior of loratadine in the body anticipate -- not just render obvious but anticipate all dosage regimens for the Kou formulation. That can't be the case.

In addition, Kou says nothing about duration, how many days, which provides an additional reason why claim 73, 74, 75 and 82 are patentable over Kou since each of them specifies about 10 days.

We believe that the examiner's error is clear from what she says at page 6 of her answer. And I quote. Thus, the Kou 274 patent would anticipate these claims wherein there is a dosage of five to 10 milligrams per day administered in a single or divided dose and the course of the precise dosage regimen may be varied depending on the requirements of the patients as well as the severity of the allergic condition being treated.

But the target is provided by the present application, not by the Kou reference. And once a skilled clinician has a target she can decide whether to administer five or 10 mgs per day or something in between in single or divided doses or decide on a different, quote, precise dosage

regimen.

The examiner's statement makes our point in other ways as well. Her statement says nothing about steady state; says nothing about the duration of treatment; says nothing about the weight of the person and even for a single day's worth of administration would result in at least four, if not more, pharmacokinetic profiles.

The examiner's problem is also highlighted by the penultimate sentence at the end of the paragraph. And I quote again. Once a reference teaching a product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency -- parenthetically, which we don't think she's done -- the burden shifts to the appellant to show an unobvious difference.

The burden has not shifted to us to show an unobvious difference. This is not an obviousness case. It's an anticipation case. The test is whether the claimed invention necessarily results from the teaching of the prior art reference. Probabilities and possibilities do not suffice.

And the Kou reference says nothing about and does not necessarily result in the target pharmacokinetic profile that is central to each of the pending claims. Thank you.

JUDGE SCHEINER: Do you have anything? Any questions? Thank you for coming in.

MR. BERMAN: Thank you.

(Whereupon, the proceedings at 9:37 a.m. were concluded.)